

Ex. 11

| QC Initls : | QC Date: | Visit #: | Visit Date | <u>ICF Version/Date</u> V2/ 13July2020 V3/ 31July2020 | Subj. # | CRC | Findings: | Corrections Completed: |
|-------------|-----------|----------|------------|---|---------|---------|---|------------------------|
| | | | | | | | | |
| AK | 8/11/2020 | 1 | 7/30/2020 | | 1001 | April | Date Format; ICF time same as VS Rest; incomplete source pages | |
| MF | 9/2/2020 | 2 | 8/20/2020 | 7/31/2020 | 1001 | Anne | 1. Confirm if consent was scanned into eConsent- paper version used. 2. Reminder- please keep progress note on top of source docs. 3. Add patient initials and ID to eDiary print out. 4. Add IMPALA drug assignment confirmation page behind page 6 of source. 5. confirm if eDC was done for V1 and add date to chart sticker if so. | |
| AK | 8/11/2020 | 1 | 7/30/2020 | | 1002 | Nika | Minor charting errors | |
| MF | 9/2/2020 | 2 | 8/20/2020 | 7/31/2020 | 1002 | Anne | 1. Add patient initials and ID to V1 and V2 eDiary printout pages. 2. Spell out "vitamin" on con med page 3. File IMPALA confirmation page behind source page 6 for V2. 4. Scan V3 consent to eConsent and make new copy of V2 consent with footer not cut-off. | |
| | | | | | 1003 | | | |
| MF | 9/2/2020 | 2 | 8/21/2020 | 7/31/2020 | 1003 | Claudia | 1. Add patient initials and ID to V1 and V2 eDiary printout pages. 2. Add late entry on progress note that V3 consent has printer smudges on the original version of the consent, that the consent language was not changed. *Discussed with Chyann who has been making consent copies for team. 3. File IMPALA confirmation page behind source page 6 for V2. 4. Scan V3 and V2 consent to eConsent. 5. Dr. Fuller to sign Progress Note for 8/22-8/23/20 ASAP. 6. V1 Vital signs page 7- please re-write the year which is not clear and initial/date correction (prior QC correction). 7. file consent process page with V3 consent- move from visit source. | |
| AK | 8/11/2020 | | 7/30/2020 | | 1004 | Linda | Date Format; ICF time same as VS Rest; Writeovers | |

| QC Initls : | QC Date: | Visit #: | Visit Date | ICF Version/Date V2/ 13July2020 V3/ 31July2020 | Subj. # | CRC | Findings: | Corrections Completed: |
|-------------|-----------|----------|------------|---|---------|-------|--|------------------------|
| MF | 9/3/2020 | 2 | 8/20/2020 | 7/31/2020 | 1004 | Anne | <p>Informed Consent process page- currently missing.</p> <p>2. Print new copy of V2 consent to include all of footer- footer is currently cut-off.</p> <p>3. Add patient initials and ID# to all eDiary log printouts.</p> <p>4. eDiary Review Log dated 7/30/20- please verify date for study day #3- appears to be a repeat of study day #4- both are dated 8/3/2020.</p> <p>5. Verify if all 3 con meds listed on con med page should be reported on the CRF- answer is yes, but should be no?</p> <p>6. answer question on page 6 V2- "Has the vaccine been administered per protocol?"</p> <p>7. answer question on page 7 V2- "Was subject in need of a new caliper or thermometer?"</p> <p>8. complete "next visit" section on page 8</p> | |
| | | | | 1005 | | | | |
| | | | | 1006 | | | | |
| AK | 8/11/2020 | | 7/30/2020 | | 1007 | Dana | Date Format; ICF time same as VS rest; | |
| MF | 9/4/2020 | 2 | 8/20/2020 | 7/31/2020 | 1007 | Anne | <p>1. Add version # to consent process page for V3 consent.</p> <p>2. scan V2 and V3 consents into eConsent.</p> | |
| | | | | 1008 | | | | |
| | | | | 1009 | | | | |
| AK | 8/11/2020 | | 7/30/2020 | | 1010 | Dana | Date Format; ICF time same as VS Rest | |
| AK | 8/11/2020 | | 7/30/2020 | | 1011 | Linda | Date Format; ICF time same as VS Rest; incomplete source pages | |
| | | | | 1012 | | | | |
| AK | 8/11/2020 | | 7/30/2020 | | 1013 | Dana | Date format; ICF time same as VS Rest | |
| | | | | 1014 | | | | |
| | | | | 1015 | | | | |
| | | | | 1016 | | | | |
| | | | | 1017 | | | | |

| QC Initls : | QC Date: | Visit #: | Visit Date | ICF Version/Date V2/ 13July2020 V3/ 31July2020 | Subj. # | CRC | Findings: | Corrections Completed: |
|-------------|-----------|----------|------------|--|---------|----------|---|------------------------|
| MF | 9/4/2020 | 1 | 7/31/2020 | 1018 | Katie | | <p>schedule.</p> <p>2. Page 9 source "childbearing potential and contraception method have been verified" is initialed but checked no for using preg not done and that it's "n/a". Please confirm which is correct- patient had tubal ligation per source.</p> <p>3. Severe reaction ediary source page- please add to page 2, "see progress note for severe reaction from ediary review log for V1".</p> <p>4. V1 page 6 source- "no" is checked for multiple systems. Confirm if they were truly not "asked about" and change to "yes" for all, if they were.</p> <p>5. Diary log printout for 8/4-8/8- Diarrhea stop date = 8/7/20 per V2 page 2 source; however, progress note on 8/8 says it stopped on 8/8 and was not severe until</p> | |
| | | | | 1019 | | | | |
| | | | | 1020 | | | | |
| | | | | 1021 | | | | |
| | | | | 1022 | | | | |
| | | | | 1023 | | | | |
| | | | | 1024 | | | | |
| | | | | 1025 | | | | |
| | | | | 1026 | | | | |
| AK | 8/13/2020 | | 8/4/2020 | | 1027 | Nika | ICF date on source;IP admin que on source; AE log; | |
| AK | 8/11/2020 | | 8/4/2020 | | 1028 | April | | |
| AK | 8/13/2020 | | 8/4/2020 | | 1029 | Nika | inconsistent date format; 3 digit entry on vital signs;subject ID # not same on source footer pages;minor charting errors; | |
| | | | | 1030 | | | | |
| AK | 8/12/2020 | | 8/5/2020 | | 1031 | Nika | PI signature missing; date format error; minor charing error | |
| AK | 8/12/2020 | | 8/5/2020 | | 1032 | Ashley | ICF time same as Progress notes; Incomplete source, Minor charting errors | |
| | | | | 1033 | | | | |
| | | | | 1034 | | | | |
| AK | 8/12/2020 | | 8/5/2020 | | 1035 | Ashley | Progress notes written (time)before ICF completion time;Minor charting errors | |
| AK | 8/13/2020 | | 8/5/2020 | | 1036 | Mercedes | Pending CRC signature;IP admin que on source; AE log header infor; | |

| QC Initials | QC Date: | Visit #: | Visit Date | ICF Version/Date V2/ 13July2020 V3/ 31July2020 | Subj. # | CRC | Findings: | Corrections Completed: |
|----------------|-----------|-------------|------------|---|---------|---------|---|---------------------------|
| | | | | | | | | Corrections Completed: |
| | | | | 1037 | | | | |
| | | | | 1038 | | | | |
| | | | | 1039 | | | | |
| | | | | 1040 | | | | |
| | | | | 1041 | | | | |
| AK | 8/13/2020 | | 8/6/2020 | | 1042 | Anne | Becca pls QC my chart | |
| | | | | 1043 | | | | |
| AK | 8/13/2020 | | 8/6/2020 | | 1044 | Katie B | Date format; IP admin que on source; CRC signature pending | |
| | | | | 1045 | | | | |
| AK | 8/13/2020 | | 8/6/2020 | | 1046 | Thea | IP admin que on source | |
| AK | 8/13/2020 | | 8/6/2020 | | 1047 | Nika | PI signature on Progress notes and CM; IP admin que in source | |
| | | | | 1048 | | | | |
| | | | | 1049 | | | | |
| | | | | 1050 | | | | |
| AK | 8/12/2020 | | 8/7/2020 | | 1051 | Katie | writeover on subject ICF name; minor charting errors;date errors | |
| | | | | 1052 | | | | |
| | | | | 1053 | | | | |
| AK | 8/13/2020 | | 8/7/2020 | | 1054 | Nika | Missing progree notes and PI signature;Incorrect ICF and IRB approval dates; Incorrect DOB; IP admin que; incomplete source pages | |
| | | | | 1055 | | | | |
| | | | | 1056 | | | | |
| | | | | 1057 | | | | |
| | | | | 1058 | | | | |
| | | | | 1059 | | | | |
| | | | | 1060 | | | | |
| AK | 8/11/2020 | | 8/7/2020 | | 1061 | Claudia | Write overs; incomplete source pages | |
| | | | | 1062 | | | | |
| AK | 8/12/2020 | | 8/7/2020 | | 1063 | Nika | incomplete source pages | |
| | | | | 1064 | | | | |
| | | | | 1065 | | | | |
| | | | | 1066 | | | | |
| | | | | 1067 | | | | |
| | | | | 1068 | | | | |
| | | | | 1069 | | | | |
| | | | | 1070 | | | | |
| | | | | 1071 | | | | |
| | | | | 1072 | | | | |
| | | | | 1073 | | | | |
| | | | | 1074 | | | | |
| | | | | 1075 | | | | |
| | | | | 1076 | | | | |

| QC Initls: | QC Date: | Visit #: | Visit Date | ICF Version/Date V2/ 13July2020 V3/ 31July2020 | Subj. # | CRC | Findings: | Correc tions Compl eted: |
|---------------|-----------|----------|---------------|--|----------|-----|--|-----------------------------------|
| KD | 8/10/2020 | 1 | ##### | V2/13July2020 signed at 0944am | 11281002 | lbl | Diary log not completed- where is the print out from eDiary dates not correct on ConMed Header on AE log no completed log EDC-?? Matching Page 5 date format not readable clearly Page 6 dates not complete Page 7- HCG kit in Lab binder? Page 9 missing initials Page 13 Visit 2 not completed | |

| | | | | | | |
|----|-----------|---|-------|--------------------------------|----------|----|
| | | | | | | |
| KD | 8/10/2020 | 1 | ##### | V2/13July2020 signed at 0948am | 11281003 | dd |
| KD | 8/10/2020 | 1 | ##### | V2/13July2020 signed at 1009am | 11281004 | ts |

| | | | | | | |
|----|-----------|---|-------|--------------------------------|----------|--|
| | | | | | | |
| KD | 8/10/2020 | 1 | ##### | V2/13July2020 signed at 1128am | 11281005 | <p>Diary log not completed- where is the print out from eDiary Header on AE log no completed log EDC-?? Matching Page 6 incomplete dates Page 7 abnormal findings- recheck? Page 8 'Other' needs to be marked "not done' Page 13 Visit 2 not completed</p> |
| KD | 8/10/2020 | 1 | ##### | V2/13July2020 signed at 1021am | 11281006 | <p>Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed EDC-?? Matching Page 1 if another CRC did this page. Would be better to have their Initials at the bottom as well. Page 6 missing date completely Page 13 Visit 2 not completed</p> |

| | | | | | | |
|----|-----------|---|-------|--------------------------------|----------|---|
| | | | | | | |
| KD | 8/10/2020 | 1 | ##### | V2/13July2020 signed at 1141am | 11281007 | <p>Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed EDC-?? Matching Page 1 PCP notification letter missing Page 6 missing date completely Page 7 - start time of rest is the same as signature of ICF-weird looking. Page 8 "other' not marked as not done' Page 13 Visit 2 not completed</p> |
| KD | 8/10/2020 | 1 | ##### | V2/13July2020 signed at 1137am | 11281008 | <p>Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed EDC-?? Matching Page 1 PCP notification letter missing Page 6 missing date completely Page 7 - start time of rest is the same as signature of ICF-weird looking. Page 8 "other' not marked as not done' Page 13 Visit 2 not completed and missing oversight signature. been 6 days since visit</p> |

| | | | | | | |
|----|-----------|---|-------|------------------------------|----------|----|
| | | | | | | |
| KD | 8/10/2020 | 1 | ##### | V2/13July2020 signed at 1359 | 11281010 | ab |
| KD | 8/10/2020 | 1 | ##### | V2/13July2020 signed at 1421 | 11281011 | dd |

| | | | | | | |
|----|-----------|---|-------|------------------------------|----------|--|
| | | | | | | |
| KD | 8/10/2020 | 1 | ##### | V2/13July2020 signed at 1519 | 11281012 | dd |
| KD | 8/10/2020 | 1 | ##### | | 11281013 | |
| | | | | | | Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed EDC-?? Matching Page 6 missing date completely Page 7 - start time of rest is the same as signature of ICF-weird looking. Page 11 AE question not marked, late entry. Page 13 Visit 2 not completed |
| KD | 8/10/2020 | 1 | ##### | V2/13July2020 signed at 1554 | 11281014 | ab |
| | | | | | | Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed-INV date is 01Aug, which is next day, so there is no late entry stating that INV checked over ConMeds during the visit. EDC-?? Matching Page 6 dates are incomplete- also missing on page 6.1 INV for late entry history Page 7 - missing rest time for BP rest period, but have an end time. Page 9 missing initial on check list Page 10- for device date is given not the device loaded on. Page 13 Visit 2 not completed |

| | | | | | | |
|----|-----------|---|----------|------------------------------|----------|---|
| | | | | | | Progress notes has a fup call regarding medical history-that should have been gotten during the visit, but was done due to queries. Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed-INV date is 01Aug, which is next day, so there is no late entry stating that INV checked over ConMeds during the visit. EDC-?? Matching Page 1, write over, that needs to be fixed Page 6 dates are incomplete- also missing on page 6 INV for late entry history from 04Aug Page 7 - missing rest |
| KD | 8/10/2020 | 1 | ##### | V2/13July2020 signed at 1606 | 11281015 | |
| KD | 8/10/2020 | 1 | 8/1/2020 | V2/13July2020 signed at 1606 | 11281016 | ts Diary log not completed- where is the print out from eDiary Header on AE log no completed log EDC-?? Matching Page 13 Visit 2 not completed |

| | | | | | | |
|----|-----------|---|----------|------------------------------|----------|--|
| | | | | | | |
| KD | 8/10/2020 | 1 | 8/1/2020 | V2/13July2020 signed at 0950 | 11281017 | dd |
| | | | | | | Progress notes Not signed off from 01Aug Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed- EDC-?? Matching Page 6 dates are incomplete- Page 9 MISSING Lab and Swab time points-- corrected with Linda Page 13 Visit 2 not completed |
| KD | 8/10/2020 | 1 | 8/1/2020 | V2/13July2020 signed at 0949 | 11281018 | |
| KD | 8/10/2020 | 1 | 8/1/2020 | | 11281019 | |

| | | | | | | |
|----|-----------|---|----------|------------------------------|----------|--|
| | | | | | | |
| KD | 8/10/2020 | 1 | 8/1/2020 | V2/13July2020 signed at 1054 | 11281020 | ab Progress notes Not signed off from 01Aug Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMed- EDC-?? Matching Page 6 dates are incomplete- INV missing from late entry 04Aug Page 10 missed check box of thermometer given. Page 13 Visit 2 not completed |
| KD | 8/11/2020 | 1 | 8/1/2020 | V2/13Jul2020 signed at 1107 | 11281021 | ts Patient information sheet not signed by subject Diary log not completed- where is the print out from eDiary Page 6 incomplete dates Page 10 Needle size confirm the right size based of WT. Page 13 Visit 2 not completed |

| | | | | | | |
|----|-----------|---|----------|-----------------------------|----------|--|
| | | | | | | |
| KD | 8/11/2020 | 1 | 8/1/2020 | V2/13Jul2020 signed at 1114 | 11281022 | ts Diary log not completed- where is the print out from eDiary Page 10 Needle size confirm the right size based of WT. Page 10 Device installed on what? Page 13 Visit 2 not completed |
| KD | 8/11/2020 | 1 | 8/1/2020 | | 11281023 | |
| | | | | | | |
| KD | 8/11/2020 | 1 | 8/1/2020 | V2/13Jul2020 signed at 1352 | 11281024 | ts Diary log not completed- where is the print out from eDiary Header on AE log no completed log Page 6 incomplete dates Page 10 Device installed on what? Page 13 Visit 2 not completed |

| | | | | | | |
|----|-----------|---|----------|-----------------------------|----------|--|
| | | | | | | |
| KD | 8/11/2020 | 1 | 8/1/2020 | V2/13Jul2020 signed at 1356 | 11281026 | ab Diary log not completed- where is the print out from eDiary Header on AE log no completed log dates not correct on ConMeds Page 6 incomplete dates Page 10 Needle size confirm the right size based of WT. Page 13 Visit 2 not completed |
| KD | 8/11/2020 | 1 | 8/1/2020 | V2/13Jul2020 signed at 1440 | 11281027 | ab Diary log not completed- where is the print out from eDiary dates not correct on ConMeds Header on AE log no completed log Page 6 incomplete dates Page 13 Visit 2 not completed |

| | | | | | | |
|----|-----------|---|----------|-----------------------------|----------|--|
| KD | 8/11/2020 | 1 | 8/1/2020 | V2/13Jul2020 signed at 1521 | 11281028 | Diary log not completed- where is the print out from eDiary dates not correct on ConMeds Header on AE log no completed log Page 6 incomplete dates Page 10 Needle size confirm the right size based of WT. Page 13 Visit 2 not completed |
| | 8/11/2020 | 1 | 8/1/2020 | V2/13Jul2020 signed at 1534 | 11281029 | Diary log not completed- where is the print out from eDiary Header on AE log no completed log Page 10 Needle size confirm the right size based of WT. Page 13 Visit 2 not completed |

| | | | | | | | |
|----|-----------|---|----------|---|----------|----|---|
| KD | 8/11/2020 | 1 | 8/3/2020 | ?missing footer for ICF-reprint signed 1033 | 11281030 | ab | Header on AE log no completed log Page 3 #11 needs to be 'No" not N/A Page 8 PE 'other' needs to be N/A Page 13 Visit 2 not completed |
| | | | | | | | Diary log not completed- where is the print out from eDiary Header on AE log no completed log Page 3 #11 needs to be 'No" not N/A Page 6 incomplete dates Page 8 PE 'other' needs to be N/A Page 9 Blood only 5ml not 25ml-Protocol deviation?? Page 13 Visit 2 not completed |
| KD | 8/11/2020 | 1 | 8/3/2020 | | 11281031 | ab | |
| | | | 8/3/2020 | | 11281032 | | |
| | | | 8/3/2020 | | 11281033 | | |
| | | | 8/3/2020 | | 11281034 | | |
| KD | 8/14/2020 | 1 | 8/5/2020 | V3/31July2020 signed at 0937 | 11281039 | ab | Diary log not completed- till 11Aug2020 ConMed page, match EDC?? Page 6 incomplete dates Page 8 'other' marked Page 10 needle size vs subject size does not match guide Page 13 Visit 2 not completed and disposition area |

| | | | | | | | |
|----|-----------|---|----------|------------------------------|----------|----|---|
| KD | 8/14/2020 | 1 | 8/5/2020 | V3/31July2020 signed at 1005 | 11281040 | dd | Diary log not completed-till 11Aug2020 ConMed page, dates incomplete match EDC?? Page 6 incomplete dates Page 10 needle size vs subject size does not match guide Page 13 Visit 2 not completed |
| KD | 8/14/2020 | 1 | 8/5/2020 | V3/31July2020 signed at 1110 | 11281043 | ts | Diary log not completed-till 11Aug2020 Page 8 'other' marked Page 13 Visit 2 not completed and disposition area |
| KD | 8/14/2020 | 1 | 8/5/2020 | V3/31July2020 signed at 1105 | 11281044 | ab | Diary log not completed-till 11Aug2020 ConMed page, incomplete match EDC?? Page 6 queries needs answering per Jerred Page 13 Visit 2 not completed |
| KD | 8/14/2020 | 1 | 8/5/2020 | V3/31July2020 signed at 1238 | 11281046 | ts | Diary log not completed-till 11Aug2020 Page 13 Visit 2 not completed |
| KD | 8/14/2020 | 1 | 8/5/2020 | V3/31July2020 signed at 1230 | 11281047 | dd | Diary log not completed-till 11Aug2020 Progress Note needs PI I&D ConMed page, match EDC?? Page 6 incomplete dates Page 10 needle size vs subject size does not match guide Page 13 Visit 2 not completed and disposition area |

| | | | | | | | |
|----|-----------|---|----------|------------------------------|----------|----|--|
| | | | | | | | |
| KD | 8/14/2020 | 1 | 8/5/2020 | V3/31July2020 signed at 1440 | 11281050 | ts | Diary log not completed-till 11Aug2020 Progress Note needs PI I&D ConMed page, incomplete dates match EDC?? AE page 1st dose missing Page 6 incomplete dates Page 10 needle size vs subject size does not match guide Page 11-device installed on ?? Page 13 Visit 2 not completed and disposition area |
| KD | 8/14/2020 | 1 | 8/5/2020 | V3/31July2020 signed at 1550 | 11281052 | ts | Diary log not completed-till 11Aug2020 Page 3 not marked E-#22 Page 13 Visit 2 not completed |
| KD | 8/14/2020 | 1 | 8/5/2020 | V3/31July2020 signed at 1551 | 11281054 | ab | Diary log not completed-till 11Aug2020 ConMed page, incompletely match EDC?? Page 6 incomplete dates Page 10 needle size vs wt Page 13 Visit 2 not completed |
| KD | 8/14/2020 | 1 | 8/5/2020 | V3/31July2020 signed at 1231 | 11281055 | ts | Diary log not completed-till 12Aug2020 ConMed page, ADHD spell out match EDC?? Page 1 missing date of signature of ICF for CRC Page 6 ADHD spell out Page 13 Visit 2 not completed |

| | | | | | | | |
|----|-----------|---|----------|------------------------------|----------|----|--|
| KD | 8/14/2020 | 1 | 8/6/2020 | V3/31July2020 signed at 1335 | 11281056 | ab | Diary log not completed-till 12Aug2020 ConMed page, incompletely match EDC?? Page 6 incomplete dates Page 13 Visit 2 not completed |
| | | | 8/3/2020 | | | | |
| KD | 8/11/2020 | | 8/7/2020 | V3/31July2020 signed at 1100 | 11281065 | | SF |
| KD | 8/11/2020 | | 8/7/2020 | V3/31July2020 signed at 1209 | 11281068 | ts | Diary log not completed-where is the print out from eDiary Page 10 missing needle size marked Page 13 Visit 2 not completed |
| KD | 8/11/2020 | | 8/7/2020 | V3/31Jul2020 signed at 0930 | 11281062 | ts | Diary log not completed-where is the print out from eDiary Page 13 Visit 2 not completed |
| KD | 8/11/2020 | | 8/7/2020 | V3/31Jul2020 signed at 1425 | 11281072 | ts | Diary log not completed-where is the print out from eDiary Page 10 Needle size was not the right size based of WT. Page 13 Visit 2 not completed |
| KD | 8/14/2020 | | ##### | V3/31Jul2020 signed | 11281109 | AS | |
| | | | | | | | |

Ex. 12

Rebecca Gibson

From: Kristi Raney <kristiraney@ventaviaresearch.com>
Sent: Thursday, September 17, 2020 4:03 PM
To: Mercedes Livingston; Kandy Downs; Olivia Ray; Brook Jackson
Cc: Marnie Fisher
Subject: Re: PFIZER-C4591001_SAE_EDP Report_subject 10961031_Initial Report_04SEP2020

How are we making sure all of these SAEs are being entered in CC? We are reimbursed \$500 per SAE. But if they aren't entered...then we are doing volunteer work

The SOMs need to be double-checking this...but just want to make sure there is a process in place for that to happen.

Kristi Raney

Managing Member, Executive Director

Ventavia Research Group

1307 8th Avenue, Suite 202
Fort Worth, TX 76104
817-348-0228 Office
817-394-1901 eFax
214-208-0390 Cell



<https://www.ventaviaresearch.com/>



<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Wednesday, September 9, 2020 12:16 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>; Kristi Raney <kristiraney@ventaviaresearch.com>
Cc: Marnie Fisher <mfisher@ventaviaresearch.com>
Subject: RE: PFIZER-C4591001_SAE_EDP Report_subject 10961031_Initial Report_04SEP2020

Thank you, Kandy.

I just checked CC to see if they SAE had been entered on the study level page for Finance to invoice for it, and it is not in CC. Please make sure HOU gets this updated as per the Operations Manual.

CC Clinical Conductor CTMS - Appointer X CC Clinical Conductor CTMS - Study X sling MY TV | Sling TV X

← → C Home ventaviaresearch.clinicalconductor.com/CCEWeb/Forms/frmSetupStudy.aspx?StudyPKey=

Apps Facebook Pinterest Email login Complion Devana Clinical Conductor ACRI

clinical conductor. SITE Menu

Study List / View Study

View Study Pfizer C4591001 Adult COVID Vaccine HOU Tran 1096 Study ID: 131

STUDY LINKS ▾

| | |
|------------------------------|-----------|
| PATIENT RELATED INFORMATION | |
| Study Patients | 623 |
| Visit Summary | 706 / 420 |
| Out-of-Window Visits | 2551 |
| Out-of-Sequence Visits | |
| Patient Management | |
| Adverse Event | 0 |
| Serious Adverse Event | 0 |
| Enrollment Efficiency | |
| Appointment Time Study | |
| Study Prospects | 0 |
| Patient Consent Summary | |
| Import/Enroll Patients | |
| Import Visit Completions | |
| ... | |
| GENERAL ITEMS | |
| Study Timeline | |
| Status History | 2 |
| Study Consents | 0 |
| Study Documents | 0 |

General Information

Pfizer C4591001 Adult COVID Vaccine HOU Tran 1096 PIN

Sponsor Team: Pfizer

Managing Site: Ventavia- Heights

Study Identifier: Pfizer C4591001 HOU

IND / IDE Number: 19736

Summary

- Contacts**
- Details**
- Settings**
- Metrics**

Identification

EDIT

Study Leadership

EDIT

Target Dates

EDIT

Recruitment

Mercedes Livingston, CCRC

Chief Operating Officer

Ventavia Research Group

1307 8th Ave Suite #202

Fort Worth, TX 76104

Cell: 817.845.3824

Office: 817.348.0228

eFax: 817.394.1901

mercedeslivingston@ventaviaresearch.com



www.ventaviaresearch.com



Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance

From: Kandy Downs <kdowns@ventaviaresearch.com>

Sent: Tuesday, September 8, 2020 10:44 AM

To: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Olivia Ray <oliviaray@ventaviaresearch.com>;

Kristi Raney <kristiraney@ventaviaresearch.com>

Cc: Marnie Fisher <mfisher@ventaviaresearch.com>

Subject: FW: PFIZER-C4591001_SAE_EDP Report_subject 10961031_Inital Report_04SEP2020

To have you all aware, since this is an extensive study. Unblinding has not occurred, not a safety concern, but the subject not able to receive 2nd dose.

Warmest Regards;

Lovica "Kandy" Downs

Regional Director

RMA, BBA, CCRC

Ventavia Research Group

1307 8th Ave Suite #202

Fort Worth, TX 76104

Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

From: Lizatte Martinez <lizattemartinez@ventaviaresearch.com>

Sent: Saturday, September 5, 2020 12:09 AM

To: Kristen.Buonocore@iconplc.com

Cc: John.Hersker@iconplc.com; 'Alfaro, Arturo A.' <Arturo.Alfaro@pfizer.com>; Houston CRC

<houcrc@ventaviaresearch.com>; Murray, Reginald <Reginald.Murray@iconplc.com>

Subject: FW: PFIZER-C4591001_SAE_EDP Report_subject 10961031_Initial Report_04SEP2020

Hi Kristen,

I received an OOO for both John and Reginald.

Just forwarding it along.

Lizatte Martinez, CCRC

Team Lead, Certified Clinical Research Coordinator

Ventavia Research Group

1919 N Loop W, Suite #250

Houston, TX 77008

Phone Number: 832-831-5349

Fax Number: 346-335-1186

Email: lizattemartinez@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

From: Lizatte Martinez <lizattemartinez@ventaviaresearch.com>

Sent: Saturday, September 5, 2020 12:05 AM

To: John.Hersker@iconplc.com

Cc: Houston CRC <houcrc@ventaviaresearch.com>

Subject: FW: PFIZER-C4591001_SAE_EDP Report_subject 10961031_Initial Report_04SEP2020

Hi John,

I got an OOO report from Reginald so thought I would forward to you.

Thanks,

Lizatte Martinez, CCRC

Team Lead, Certified Clinical Research
Coordinator

Ventavia Research Group

1919 N Loop W, Suite #250

Houston, TX 77008

Phone Number: 832-831-5349

Fax Number: 346-335-1186

Email: lizattemartinez@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

From: Lizatte Martinez <lizattemartinez@ventaviaresearch.com>

Sent: Saturday, September 5, 2020 12:02 AM

To: Murray, Reginald <Reginald.Murray@iconplc.com>

Cc: 'Alfaro, Arturo A.' <Arturo.Alfaro@pfizer.com>; May, Nancy <Nancy.May@iconplc.com>; Houston CRC <houcrc@ventaviaresearch.com>; Van Tran <vantran@ventaviaresearch.com>

Subject: PFIZER-C4591001_SAE_EDP Report_subject 10961031_Initial Report_04SEP2020

All,

Please note that at visit 2-subject 10961031 was noted to have a positive pregnancy test result PRIOR to vaccination.

Site became aware at 15:58 CST on 04 SEP 2020.

SAE Report and EDP form was completed and Faxed to sponsor on 04 SEP 2020 at 23:52 CST.

EDC was updated at 23:40 CST on 04 SEP 2020.

To confirm-subject did not receive vaccination 2 AND had a negative urine pregnancy test result on 14 AUG 2020 PRIOR to receiving vaccination 1.

Subject has agreed to stay on trial for follow up and is aware she will no longer receive treatment.

*****Of note, there is NO EDP template or FAX Cover sheet templates in Firecrest or in previous correspondence to site. These were requested from Nancy today however, I did NOT delay reporting because of this. I used a Pfizer EDP template from another study to submit and a Ventavia Fax coversheet Template.**

Lastly, I am attaching all the documents that were faxed today for your convenience.

Thanks again,

Lizatte Martinez, CCRC

Team Lead, Certified Clinical Research Coordinator

Ventavia Research Group

1919 N Loop W, Suite #250

Houston, TX 77008

Phone Number: 832-831-5349

Fax Number: 346-335-1186

Email: lizattemartinez@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

Ex. 13

Rebecca Gibson

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Tuesday, September 22, 2020 10:19 AM
To: Brook Jackson; Jen Vasilio
Cc: Katie Buchanan
Subject: RE: Performance forms- FYI

Hi ladies,

Did the write-ups get done with Nadia and Jailyn? Copying Katie so she's in the loop as well.

Thanks,
Marnie

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Friday, September 18, 2020 2:42 PM
To: Marnie Fisher <mfisher@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>
Subject: RE: Performance forms- FYI

For the Jailyn and Nadia report-

Back in Aug- during a routine stop in FW- Kandy observed COVID IP boxes left out on the counter, full exposed to anyone that entered the room could see.

The current SOM was notified, then both unblinded CRC's were notified of finding. Kandy then reviewed the process of having IP boxes broken down and reminded that the IP boxes which has patient information have to be securely placed up as patient's are dosed.

The boxes were then broken down, and placed in secured black tote for storage. Both CRC's verbally understood the blinding process. No training was documented, or other communication was given.

RD Kandy Downs

Warmest Regards;

Lovica "Kandy" Downs

Regional Director
RMA, BBA, CCRC

Ventavia Research Group

1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

From: Marnie Fisher <mfisher@ventaviaresearch.com>

Sent: Friday, September 18, 2020 2:33 PM

To: Brook Jackson <bjackson@ventaviaresearch.com>; William Jones <wjones@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>

Subject: Performance forms- FYI

I wanted to make sure you all had these forms.

Regards,
Marnie

Marnie Fisher

Director of Operations, MBA, BSN, RN

Ventavia Research Group

1307 8th Ave Suite #202

Fort Worth, TX 76104

Cell Number: 817.269.3768

eFax Number: 817.394.1901

Email: mfisher@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

Ex. 14



Note to File

Principal Investigator: XXXXX, XX

Protocol: C4591001

Site Number: XXX

Date: September 17, 2020

Regarding: IMPALA Randomization and drug assignment confirmation printouts in research charts

This Note to File serves as notification that confirmation printouts of research participant drug assignments will not be placed within participant charts for study C4591001. Inclusion of the drug assignment confirmation will disclose drug dosage information contraindicated for study blinding. It is for this purpose that the confirmation of drug assignment is located in Complion within the unblinded binder. This note to file addresses IMPALA drug assignment confirmation requested in study source document versions 1 through 5.

An update the source document removing this requirement has been created in follow-up to this Note to File.

1307 8th Avenue
Suite 202
Fort Worth, TX 76104

Signature: Director QA/QC, Regulatory, Training

Date

Signature: Investigator

Date

Ex. 15

Rebecca Gibson

From: Kandy Downs <kdowns@ventaviaresearch.com>
Sent: Friday, September 18, 2020 2:00 PM
To: William Jones; Marnie Fisher
Cc: Brook Jackson
Subject: FW: Pfizer_C4591001_COVID-19

Importance: High

It was confirmed with Arturo that the Randomization form is not to be filed with the blinded source. This has time points that would allow for unblinding potential.

Warmest Regards;

Lovica "Kandy" Downs

Regional Director
RMA, BBA, CCRC

Ventavia Research Group

1307 8th Ave Suite #202
Fort Worth, TX 76104
Cell Number: 817-269-5997
eFax Number: 817.394.1901
Email: kdowns@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

From: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>
Sent: Friday, September 18, 2020 1:35 PM
To: Kandy Downs <kdowns@ventaviaresearch.com>
Cc: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Subject: RE: Pfizer_C4591001_COVID-19

Confirmed.

Arturo A. Alfaro, M.D.
Site Relationship Partner II
Global Site & Study Operations
Clinical Development & Operations, GPD
Location: North America, United States, C.S.T.
Office / Cell: 512-638-2188

Fax: 845-474-5793

arturo.alfaro@pfizer.com



Breakthroughs that
change patients' lives

From: Kandy Downs <kdowns@ventaviaresearch.com>

Sent: Friday, September 18, 2020 1:31 PM

To: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>

Cc: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>

Subject: [EXTERNAL] Pfizer_C4591001_COVID-19

Hello Arturo;

Thank you for talking with.

Can you confirm that the Randomization from IMPAL is NOT to be given to BLINDED.

Warmest Regards;

Lovica "Kandy" Downs

Regional Director

RMA, BBA, CCRC

Ventavia Research Group

1307 8th Ave Suite #202

Fort Worth, TX 76104

Cell Number: 817-269-5997

eFax Number: 817.394.1901

Email: kdowns@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

From: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>

Sent: Monday, September 14, 2020 9:42 AM

To: Rebecca Iacullo <rebeccaiaacullo@ventaviaresearch.com>

Cc: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kathryn Weems

<kathrynweems@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher

<mfisher@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>

Subject: RE: Pfizer_C4591001_COVID-19_Amend 6 Question

Hi Rebeca;

Once amendment # 6 is approved, patients with known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) can be included.

Arturo A. Alfaro, M.D.

Site Relationship Partner II

Global Site & Study Operations

Clinical Development & Operations, GPD

Location: North America, United States, C.S.T.

Office / Cell: 512-638-2188

Fax: 845-474-5793

arturo.alfaro@pfizer.com



From: Rebecca Iacullo <rebeccaiaacullo@ventaviaresearch.com>

Sent: Monday, September 14, 2020 9:20 AM

To: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>

Cc: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Kathryn Weems <kathrynweems@ventaviaresearch.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Brook Jackson <bjackson@ventaviaresearch.com>

Subject: [EXTERNAL] Pfizer_C4591001_COVID-19_Amend 6 Question

Good Morning Arturo,

I am working on updating source documents for the 3 Ventavia sites so when Amendment 6 is approved we will be ready. As I was reading through the changes for the inclusion exclusion criteria, I am needing some clarification.

In Amendment 6, Inclusion 3 states "Healthy participants who are determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for inclusion in the study.

Note: Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, can be included. Specific criteria for **Phase 3** participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) can be found in Section 10.8."

Exclusion 2 states "**Phases 1 and 2 only:** Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)."

However, per protocol phase 2 and 3 are still combined (Phase 2/3). Those 2 criteria seem to contradict each other. Can you please provide some clarification if patients with HBV/HCV/HIV are excluded from the study for phase 2/3? Thank you!

Best Regards,

Becca

Rebecca Iacullo, B.S., CCRC

Ventavia Research Group

1307 8th Ave. Suite 202

Fort Worth, Texas 76104

Cell: 210-861-6912

rebeccaiaacullo@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

Ex. 16

Brook Jackson

From: Cordy Henslin <cordyhenslin@ventaviaresearch.com>
Sent: Tuesday, September 15, 2020 8:25 AM
To: Brook Jackson
Subject: Fw: UNBLINDING - C4591001 | 1085/Fuller Follow-up

Sincerely,

Cordelia "Cordy" Henslin

CRC, Recruitment Specialist, MA

Ventavia Research Group

300 N Rufe Snow DR

Keller, TX 76248

Phone Number: [\(682\)774-8013](tel:(682)774-8013)

Fax Number: [\(817\)337-3224](tel:(817)337-3224)

Email: cordeliataylor@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Notice:

Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

From: Collins, Jayton <Jayton.Collins@iconplc.com>
Sent: Friday, August 14, 2020 15:32
To: Cordelia Taylor <cordeliataylor@ventaviaresearch.com>
Cc: jinamartinez@nhfm.net <jinamartinez@nhfm.net>
Subject: UNBLINDING - C4591001 | 1085/Fuller Follow-up

Hi Cordy,

As previously mentioned on our phone call today, here is a summary/list of items to review:

- Shipment Receipt Invoices need added to Complion for review.
- Jina needs to complete Protocol Amendment 4 & 5 trainings in Firecrest. You need to complete Protocol Amendment 5.
- Both need to complete the V5 training: IP Preparation, Reconstitution, and Administration.
- CVs for you and Jina need filed. GCP & Impala training certificate needs filed.
- **URGENT: Jina needs to Read & Acknowledge the IP documents flagged for her in Firecrest. This needs to be done ASAP.**
- **URGENT: Temperature logs/records need uploaded to Complion.**
- Blinding Plan & Secrecy Agreement need loaded to Complion.
- Reminder: Kit Verification App can be used on b2 and placebo IPAL and first Drug Assignment report from Impala (subsequent doses need the second verification signature). When used, please indicate usage by writing, "KV#2."
- Various preparation records are missing from Complion, but specifically for the following subjects: 10851012, 10851016, 10851028, 10851032, 10851035, 10851036, 10851061, 10851073, and 10851082.
- Placebo IPAL is good—I didn't note any issues. Disposition section needs completed upon destroying the vial. **Reminder: save the carton. You may break this down and flatten it, but ensure the label is not harmed & is still legible. This goes for all IP containers.**
- Preparation Record for 10851001, 10851005, 10851007, and 10851008 indicates a volume of 1.7mL Sodium Chloride was withdrawn instead of 1.2mL. You indicated this was likely a transcription error due to the final volume needing to be 1.7mL. Please correct this preparation record and replace the one in Complion with the updated copy.
- Yellow b2 IPAL:
 - o No disposition is documented. Please ensure this is performed (with double verification) and document.
 - o The Dispensed column is completed incorrectly. Those that were dispensed b2 from a vial already dispensed need to have it indicated as "N/A" instead of "D-1."
 - o Subject 10851029 is not documented on the IPAL (Container 046173).
 - o Below is a screenshot of an example b2 IPAL. Note the Dispensed Column and the Disposition columns:

| | | | |
|---|--|--|---|
| Protocol Title: A PHASE 1/2/3 PLACEBO-CONTROLL DOSE-FINDING STUDY TO EVALUATE THE SAFET AND EFFICACY OF SARS-COV-2- RNA VACCINE C HEALTHY ADULTS | | | |
| Site Principal Investigator: | | | |
| Investigational Medicinal Product Name: | | | Str |
| BNT162b2 Vaccine (YELLOW LABEL) | | | 250 |
| Units Per Container: | | | |
| 1 vial per carton | | | |
| Receipt or Dispense Date dd/Mmm/yyyy | <input type="checkbox"/> Lot Number <input type="checkbox"/> Kit Number <input checked="" type="checkbox"/> Container Number <input type="checkbox"/> Other (specify) <hr/> Or Shipment ID # ⁴ | Study Subject ID Number (SSID) ⁵ | Quantity of Containers Received (R) or Dispensed (D) or Undispensed (U) ⁶ |
| 05JUN2020 | Shipment ID 1234567 | | R+8 |
| 08JUN2020 | 8856796 | 1001- 1001 | D-1 |
| 08JUN2020 | 8856796 | 1001- 1002 | N/A |

- Diluent IPAL is done incorrectly. It needs to mimic the b2 IPAL—each subject dosed from a vial that used diluent needs documented. Here is a screenshot of an example of a completed diluent log:

Protocol Title: A PHASE 1/2/3 PLACEBO-CONTROLED FINDING STUDY TO EVALUATE THE SAFETY AND EFFICACY OF SARS-COV-2- RNA VACCINE IN ADULTS

Site Principal Investigator:

Investigational Medicinal Product Name:

DILUENT: 0.9% Sodium Chloride Injection,

Units Per Container:

25 vials per tray

| Receipt or Dispense Date ³ dd/Mmm/yyyy | <input checked="" type="checkbox"/> Lot Number <input type="checkbox"/> Kit Number <input type="checkbox"/> Container Number <input type="checkbox"/> Other (specify) Or Shipment ID # ⁴ | Study Subject ID Number (SSID) ⁵ | R 1 0 |
|---|---|--|-------------|
| 05JUN2020 | Lot Number 12999 | | |
| 08JUN2020 | 12999 | 1001- 1001 | |
| 08JUN2020 | 12999 | 1001- 1002 | |

Note: Both participants were dosed from the same active vial

Please let me know if you have any other questions/concerns. All of these will be documented in the follow-up letter that will be sent out early next week as well.

Thanks!!

Jayton Collins
Clinical Research Associate I
Clinical Research Service

Mobile: +1 469-785-0977
Jayton.Collins@iconplc.com
www.ICONplc.com



ICON plc made the following annotations.

This e-mail transmission may contain confidential or legally privileged information that is intended only for the individual

or entity named in the e-mail address. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or reliance upon the contents of this e-mail is strictly prohibited. If you have received this e-mail transmission in error, please reply to the sender, so that ICON plc can arrange for proper delivery, and then please delete the message.

Thank You,

ICON plc
South County Business Park
Leopardstown
Dublin 18
Ireland
Registered number: 145835

Ex. 17

Rebecca Gibson

From: Marnie Fisher <mfisher@ventaviaresearch.com>
Sent: Monday, September 21, 2020 5:13 PM
To: Mercedes Livingston; Kandy Downs; Brook Jackson; William Jones
Subject: Common findings/Action Plan- all sites

This is really rough- I had so many distractions trying to type this up, but hopefully, it's a helpful start:

| Finding of Concern: | Details of Findings: | Solution (QUICK FIX): | Comments: |
|---|--|--|---|
| HIPAA Violations | Sites not consistent with protecting PHI- PHI left on desks (FW front desk example); patient schedule with patient names left on counter faced up; patient folders out on counters in the clinic and faced up with names visible; emails with patient names in the subject line. | <ol style="list-style-type: none"> 1. RDs to observe and correct at sites when onsite- discuss/re-educated with employees at the site as concerns are found. 2. "Audit Readiness" training- I think we still need this for sites quickly, and we HIPAA can be included. | Where are we with HIPS training? |
| Outdated Protocol Pages in Patient Folders | Sites are not keeping the Schedule of Events pages in the patient folders current and some copies are so poorly printed that they are completely illegible, defeating the purpose of them being placed in the chart. | <ol style="list-style-type: none"> 1. Pull all protocol pages out of all charts. 2. Reassess the process for future studies. | |
| AEs Not Reported | AEs from diary entries are not being reported correctly or at all- 1. Protocol is unclear; 2. Conflicting information received from Pfizer | <ol style="list-style-type: none"> 1. We need to get an official direction from Pfizer. Email from ICON received but the email was not clear as well and not an official "Clarification" or "Addendum" or even a "Memo". 2. For now, we should follow the protocol as to how we read it and record any AEs ASAP- may need to split the patients up for staff to verify. 3. Anyone doing QC should be looking for potential AEs not caught during study visits and flag them for correction. | Email from ICON dated 8/17/20. FUTURE: revise AE log |

| | | | |
|--|---|--|--|
| | | <p>4. Once we have clarification- train all staff.</p> | |
| Injection Wait Time Discrepancy (<30 mins) | Injection wait times have been found to be less than 30 mins without any explanation. | <p>1. Site staff needs to correct ASAP- add a note to explain why the time was less than 30 mins and submit deviations accordingly.</p> <p>2. We need an NTF to explain that we caught the errors and implemented an action to prevent this moving forward, for example, FW implemented the use of timers.</p> | Long term- need to conduct re-training on why this is so critical |
| IP Storage | IP rooms are disorganized, drug/placebo and saline are not being kept locked- no double lock in place at Keller or FW? Not sure about Houston. Keller had kit #s that were transcribed incorrectly and a CAPA was written. | <p>1. RDs and staff at site to get these rooms cleaned up and organized; drug locked up and keys place in a separate place than the IP room and secured- need to have documentation of this process as well- who has keys, etc.</p> <p>2. Keller- quick fix for a double lock is to place all loose drug currently in the refrigerator in locked boxes as well- the freezer is already a double-lock system.</p> | Long term- get locks placed on doors to IP room. |
| Informed Consent Errors | <p>1. Consent being done during the protocol-required “5 mins of wait time”.</p> <p>2. Paper consents used were not being scanned into eConsent.</p> <p>3. Several of the paper consents that were used, as opposed to electronic, were printed with a large number of artifacts on the copies and appeared to have wording present that truly wasn’t present.</p> <p>4. Some consents were printed or copied with the footers missing.</p> <p>5. Consent process page- inconsistently being filed with visit and sometimes with consent.</p> | <p>1. NEED CLARIFICATION IF THIS IS OKAY OR NOT (#1). If not, we need staff to explain the atmosphere and patient status during the consent process and complete deviations if warranted.</p> <p>2. Need to scan in all paper consents to eConsent ASAP, if not done already.</p> <p>3. Correct consent issues and note changes being made in progress notes where needed. NTF for</p> | <p>Long term- re-training as stated above, on documentation practices.</p> <p>Change process for process page of consent- consider adding this as page 1 of ALL consents, versus the visit source.</p> |

| | | | |
|-----------------------|---|---|--|
| | <p>6. Amendment #6- I'm told some patients are not being re-consented, but it sounds like it's required?</p> | <p>errors and corrective action??</p> <p>4. Confirm if re-consent is needed for Amend #6.</p> <p>5. Document re-training</p> | |
| Progress Notes | <p>1. Inconsistencies in its use and doesn't always match what's being documented in the source.</p> <p>2. Progress Note form requires a "time" in the header but time is not being recorded.</p> | <p>1. Flag corrections needed to notes</p> <p>2. Remove "time" and state "N/A"?</p> | Future- suggest creating a progress note page specific to each visit, as opposed to one running log. |
| Source Errors | <p>1. Contraception Check: "NA" checked for menopausal/hysterectomy patients but the signature at the bottom of this section is also signed, which states a "subject agrees to maintain birth control, etc."</p> | <p>1. V2 Source: For patients who are confirmed to be post-menopausal or have had a hysterectomy- cross through signature and write "error- the patient is confirmed to be post-menopausal, etc.. or "error- the patient has had a hysterectomy".</p> <p>2. V1 Source: same section but also has investigator signature- handle in the same manner.</p> | Long Term- re-create source templates |
| Other Findings | <p>2. Sticky notes on top of the patient charts not being consistently completed.</p> <p>3. Deviations- not sure they are getting completed or not- need to verify all items above mentioned.</p> <p>4. Visit 2s- some are out of window due to staff following CC which hadn't been updated until 9/18/20.</p> | <p>3. Charts are being flagged to complete sticky notes- reeducating staff as well to always complete this.</p> <p>4. CC has been updated, need to verify upcoming V2s are in window- if many deviations, may need to do a NTF to explain why they were out of window?</p> | Overall training needed- Research 101 training, in particular documentation practices. |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Marnie Fisher

Director of Operations, MBA, BSN, RN

Ventavia Research Group

1307 8th Ave Suite #202

Fort Worth, TX 76104

Cell Number: 817.269.3768

eFax Number: 817.394.1901

Email: mfisher@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

Ex. 18

Common QA Findings – Pfizer C4591001**Subject Number:** _____****PLEASE FILE ALL NTFs IN THE PATIENT'S CHART ON THE RIGHT SIDE OF CHART BEHIND PROGRESS NOTES****

| ICF | Reviewed | Finding |
|---|--------------------------|--------------------------|
| Current version of ICF is used | <input type="checkbox"/> | <input type="checkbox"/> |
| Signatures are consistent with no obvious mismatch | <input type="checkbox"/> | <input type="checkbox"/> |
| Correct dates used by the patients | <input type="checkbox"/> | <input type="checkbox"/> |
| Printer copies are clear (not sloppy, cutting off footers, etc) | <input type="checkbox"/> | <input type="checkbox"/> |
| Consistency in where the ICF documentation process form is kept | <input type="checkbox"/> | <input type="checkbox"/> |
| Screening ICF document is embedded in the screening source | <input type="checkbox"/> | <input type="checkbox"/> |
| Re-consent ICF documentation is on top of the revised ICF | <input type="checkbox"/> | <input type="checkbox"/> |
| ICF documentation form comment section documents any questions and answers | <input type="checkbox"/> | <input type="checkbox"/> |
| Updated ICF documentation page has blanks for the CRC initials instead of checkboxes | <input type="checkbox"/> | <input type="checkbox"/> |
| ICF was checked for Quality Assurance by the consenter | <input type="checkbox"/> | <input type="checkbox"/> |
| Proper ICF QC process | <input type="checkbox"/> | <input type="checkbox"/> |
| Verify that any paper consent used have been scanned into eConsent | <input type="checkbox"/> | <input type="checkbox"/> |
| Progress Noting | Reviewed | Finding |
| Anything out of the ordinary is explained in the progress note | <input type="checkbox"/> | <input type="checkbox"/> |
| Initials are consistent with the subject information sheet, or progress noted | <input type="checkbox"/> | <input type="checkbox"/> |
| Typically acute AEs or CMs are explained if ongoing from visit to visit | <input type="checkbox"/> | <input type="checkbox"/> |
| Schedule of Events | Reviewed | Finding |
| Remove from charts all together (do not replace with new ones) | <input type="checkbox"/> | <input type="checkbox"/> |
| Verify Visits 2 and beyond dates are within window (Print the Firecrest Visit Scheduler and place copy on left side of chart on top of Patient Information Sheet) | <input type="checkbox"/> | <input type="checkbox"/> |
| Randomization Confirmations | Reviewed | Finding |
| Randomization confirmations needs to come out of the charts and line through file instructions in source and state "see NTF". File NTF in each chart | <input type="checkbox"/> | <input type="checkbox"/> |
| Drug assignments need to come out (if they were in there) and line through file instructions in source and state "see NTF". File NTF in each chart | <input type="checkbox"/> | <input type="checkbox"/> |
| Write Overs | Reviewed | Finding |
| CRC correctly making changes (line through, initial, date) | <input type="checkbox"/> | <input type="checkbox"/> |
| Patients making changes correctly on Consents (line through, initial, date) | <input type="checkbox"/> | <input type="checkbox"/> |
| Source Version | Reviewed | Finding |
| Using correct, most current version of source (verify version date) | <input type="checkbox"/> | <input type="checkbox"/> |

Common QA Findings – Pfizer C4591001

Subject Number: _____

| | | |
|--|--------------------------|--------------------------|
| KELLER- Add NTF to each chart for using wrong source versions | | |
| Risk Factors | Reviewed | Finding |
| Consistent with demographics | <input type="checkbox"/> | <input type="checkbox"/> |
| Those that need to go in MedHx are listed there | <input type="checkbox"/> | <input type="checkbox"/> |

| | | |
|--|--------------------------|--------------------------|
| Visits Procedures | Reviewed | Finding |
| Conducted in a stepwise manner, per protocol | <input type="checkbox"/> | <input type="checkbox"/> |
| Source Completion | Reviewed | Finding |
| No blanks in charts | <input type="checkbox"/> | <input type="checkbox"/> |
| CM Logs | Reviewed | Finding |
| Indication matches medical history | <input type="checkbox"/> | <input type="checkbox"/> |
| MedHx start dates and CM start dates line up (example; med shouldn't start prior to condition) | <input type="checkbox"/> | <input type="checkbox"/> |
| Contraception in WOCBP | Reviewed | Finding |
| Added to con meds and/or med history | <input type="checkbox"/> | <input type="checkbox"/> |
| Tubal ligation- documenting bilateral, etc | <input type="checkbox"/> | <input type="checkbox"/> |
| Source Document of WOCBP | Reviewed | Finding |
| Signature statement only signed if the subject's methods of contraception could change while in the study (ADD NTF to each chart that will address discrepancy of signature statement)- DO NOT CROSS OUT SIGNATURES NOW | <input type="checkbox"/> | <input type="checkbox"/> |
| Medical History | Reviewed | Finding |
| Prior source versions had "Yes/No" boxes for each body system- verify that "yes" was checked for ALL systems. (Have CRC correct this and write a note confirming that all systems were assessed at the visit, however, the question was misread initially and only the body system that the patient has a medical history in, was checked). | <input type="checkbox"/> | <input type="checkbox"/> |
| VERSION #5 is most current- should check "yes" that all body systems have been asked about. | | |
| Procedures listed in MedHx along with indication for procedure | <input type="checkbox"/> | <input type="checkbox"/> |
| Devices | Reviewed | Finding |
| Device and/or app changes and issues documented clearly (e.g., Subject requested a device at screening visit. At next visit, requested to use the app. No documentation on the progress note.) | <input type="checkbox"/> | <input type="checkbox"/> |
| E-diary and AEs | Reviewed | Finding |
| Symptoms noted in the e-diary regardless of if they are ongoing after Day 7 are not to be reported as AEs | <input type="checkbox"/> | <input type="checkbox"/> |

Common QA Findings – Pfizer C4591001**Subject Number:** _____

| | | |
|--|--------------------------|--------------------------|
| Patients outside of the reactogenicity subset if they have symptoms after vaccine should be reporting in the illness visit e-diary page and not as AEs | <input type="checkbox"/> | <input type="checkbox"/> |
| E-diary Printouts | Reviewed | Finding |
| E-diaries are printed on Day 8 (after 7 day period) and signed by the PI as soon as possible (within 2-3 days from printing) | <input type="checkbox"/> | <input type="checkbox"/> |
| Patient ID/initials and Study number are on the e-diary print-out | <input type="checkbox"/> | <input type="checkbox"/> |
| Weekly eDiary review log completed | <input type="checkbox"/> | <input type="checkbox"/> |

Additional findings: NA

| Source | Reviewed | Finding (list below) |
|--------|--------------------------|----------------------|
| | <input type="checkbox"/> | |

Signature/Date of QC person reviewing: _____

Common QA Findings – Pfizer C4591001

Subject Number: _____

Date given to RD: _____ Name of RD:

Ex. 19

Rebecca Gibson

From: Casteel, Crystal <Crystal.Casteel@iconplc.com>
Sent: Monday, September 21, 2020 11:44 AM
To: Marnie Fisher; Kandy Downs; Brook Jackson
Cc: Mercedes Livingston; Rebecca Iacullo; Michelle Vernon; Katherine Benitez; CRC; Plano CRC; Grapevine; Dallas; Arlington; Ramirez, Rebecca; Stella Alawuru (Stella.Alaw@pfizer.com); Furlow, Danielle; Casteel, Crystal; Gilliam, Melissa; Taylor, JoAnn; Diggs, Sylvia
Subject: RE: Pfizer C3671008 | Crystal's Ventavia Sites | Consider Source Revisions: BMI, ICF Process Documentation, Lab Collection

Hi Marnie, Kandy, and Brook,

I wanted to follow-up to see if there **has there been any internal discussions regarding the ICF documentation considerations I mentioned below?**

Additionally, I have one more possible suggestion. I've re-reviewed the Lab Collection section of your source worksheets and I wanted to know if you all **have a separate document that details the collection & processing times that may not been previously provided?**

CRAs must confirm that sites are in compliance with the "Blood Specimen Chain of Custody". Our protocol (section 8.1.4 Immunogenicity Assessment) spells out that each specimen should be drawn and processed as indicated in the Lab manual:

1. Draw blood
2. Allow the blood to clot at room temperature for a minimum of 30 minutes and a maximum of 2 hours.
3. Separate the serum by centrifugation at room temperature at 1,000 to 1,300 g (check the correct RPM is selected) for 10 to 15 minutes.
4. Remove the serum from the Vacutainer® tubes using a sterile transfer pipette to sterile cryovials (up to the 1.8 mL graduation). Transfer serum into 2 **SEND** cryovials (remaining serum will go into cryovials designated as **RETAIN**).
5. Samples must be stored in a manual defrost freezer at -15 °C or colder.

FDA requires that any specimen collected have documentation to prove that the protocol requirements were followed. Without this proof, it's plausible that specimens could be removed/disallowed from our analyses.

So – each site can document either in a lab log or directly in subject source documents the following details:

- The time a required specimen was drawn (and by whom at the site)
- The length of time the specimen(s) were allowed to sit at room temp (start and stop is ideal, but at least some documentation that site complied with specimen handling from A-Z is necessary).
- The time specimens were spun down (per protocol)
- The time specimens were separated and frozen

OR a comprehensive comment can be recorded confirming that the lab specimens were collected and processed per the protocol and lab manual.

If you all have not previously collected this information, **would you consider updating your lab collection question per the screenshot below to note: Was pre-vaccination blood draw for serologic assessment (~ 15 ml) collected "and processed according to the protocol/lab manual?"**

This WAS a finding in one of my current Pfizer studies and sites were required to provide or update 3 years later. You all can imagine the workload this created.....so I would like to avoid this being an issue during this study and ensure this isn't a finding for any of my sites.

Pfizer C3671008 Source Documents Version 2 17Jun2020KW Site 1028 PI: Cynthia Robbins, MD
Screening and Vaccination (Visit 1) Day -28 to Day 1

Lab Collection Not Done

Was pre-vaccination blood draw for serologic assessment (~15ml) collected?
(pre-vaccination blood collection should take place on the same day or within 7 days before the vaccination visit).

Yes No, reason: _____

Date collected: 07.Jul.2020 (dd/mmm/yyyy) Time collected: 11:56 (24hr)

Kind regards,
Crystal

Crystal Casteel
Senior Clinical Research Associate
Clinical Research Service

Mobile: +1 972-515-0460
Email: Crystal.Casteel@iconplc.com
Web: www.ICONplc.com



PSBU - Partnering Excellence for a Healthier World!

Our team is making a difference by advancing research in the fight against COVID-19
www.iconplc.com/vaccines/

If you need to report a Serious Adverse Event (SAE):

For a Pfizer study, please fax your SAE report to +1.866.997.8322;

For Non-Pfizer studies, please call the SAE Hotline at +1.888.426-8801.

Please DO NOT send SAE information via this email address.

From: Casteel, Crystal <Crystal.Casteel@iconplc.com>

Sent: Tuesday, September 1, 2020 1:59 PM

To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Rebecca Iacullo <rebeccaiaacullo@ventaviaresearch.com>; Michelle Vernon <michellevernon@ventaviaresearch.com> <michellevernon@ventaviaresearch.com>; Katherine Benitez <katherinebenitez@ventaviaresearch.com>

Cc: Fort Worth CRC Ventavia Group Email <crc@ventaviaresearch.com> <crc@ventaviaresearch.com>; Plano CRC Ventavia Group Email <planocrc@ventaviaresearch.com> <planocrc@ventaviaresearch.com>; Grapevine CRC Ventavia Group Email <grapevinecrc@ventaviaresearch.com> <grapevinecrc@ventaviaresearch.com>; Dallas CRC Ventavia Group Email <dallascrc@ventaviaresearch.com> <dallascrc@ventaviaresearch.com>; Arlington CRC Ventavia Group Email <arlingtoncrc@ventaviaresearch.com> <arlingtoncrc@ventaviaresearch.com>; Ramirez, Rebecca <Rebecca.Ramirez@iconplc.com>; Stella Alawuru <Stella.Alaw@pfizer.com> <Stella.Alaw@pfizer.com>; Furlow, Danielle <Danielle.Furlow@iconplc.com>; Casteel, Crystal <Crystal.Casteel@iconplc.com>

Subject: RE: Pfizer C3671008 | Crystal's Ventavia Sites | Consider Source Revisions: BMI & ICF Process Documentation

Hi Mercedes,

Thank you very much for discussing this internally, considering my input, and confirming that your BMI documentation will remain unchanged.

Has there been any discussion regarding the ICF documentation considerations?

- I wanted this to be an open discussion and provide you all with suggestions as this was never a directive. If this documentation will remain unchanged, are all SCs aware of what dates need to be captured to avoid queries?
 - o What will you all capture for the "ICF Date" for all sites – the ICF version date or the ICF revised version date?

Thanks,
Crystal

Crystal Casteel
Senior Clinical Research Associate
Clinical Research Service

Mobile: +1 972-515-0460
Email: Crystal.Casteel@iconplc.com
Web: www.ICONplc.com



PSBU - Partnering Excellence for a Healthier World!

Our team is making a difference by advancing research in the fight against COVID-19
www.iconplc.com/vaccines/

If you need to report a Serious Adverse Event (SAE):
For a Pfizer study, please fax your SAE report to +1.866.997.8322;
For Non-Pfizer studies, please call the SAE Hotline at +1.888.426-8801.
Please DO NOT send SAE information via this email address.

From: Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>
Sent: Sunday, August 30, 2020 6:58 PM
To: Casteel, Crystal <Crystal.Casteel@iconplc.com>; Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Rebecca Iacullo <rebeccaicacullo@ventaviaresearch.com>; Michelle Vernon <michellevernon@ventaviaresearch.com>; Katherine Benitez <katherinebenitez@ventaviaresearch.com>
Cc: CRC <CRC@ventaviaresearch.com>; Plano CRC <planocrc@ventaviaresearch.com>; Grapevine <grapevinecrc@ventaviaresearch.com>; Dallas <dallascrc@ventaviaresearch.com>; Arlington <arlingtoncrc@ventaviaresearch.com>; Ramirez, Rebecca <Rebecca.Ramirez@iconplc.com>; Stella Alawuru <Stella.Alaw@pfizer.com> <Stella.Alaw@pfizer.com>; Furlow, Danielle <Danielle.Furlow@iconplc.com>
Subject: RE: Pfizer C3671008 | Crystal's Ventavia Sites | Consider Source Revision for BMI

Crystal

We will continue to put the actual BMI number as we have in the source vs a yes or no checkbox. A yes or no checkbox leaves us open to way more errors if the CRC isn't documenting the actual BMI number.

Thanks,

Mercedes Livingston, CCRC
Chief Operating Officer

Ventavia Research Group

1307 8th Ave Suite #202

Fort Worth, TX 76104

Cell: 817.845.3824

Office: 817.348.0228

eFax: 817.394.1901

mercedeslivingston@ventaviaresearch.com



www.ventaviaresearch.com



Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance

From: Casteel, Crystal

Sent: Wednesday, August 26, 2020 11:27 AM

To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Rebecca Iacullo <rebeccaiaacullo@ventaviaresearch.com>; Michelle Vernon (michellevernon@ventaviaresearch.com) <michellevernon@ventaviaresearch.com>; Katherine Benitez <katherinebenitez@ventaviaresearch.com>

Cc: Fort Worth CRC Ventavia Group Email (crc@ventaviaresearch.com) <crc@ventaviaresearch.com>; Plano CRC Ventavia Group Email (planocrc@ventaviaresearch.com) <planocrc@ventaviaresearch.com>; Grapevine CRC Ventavia Group Email (grapevinecrc@ventaviaresearch.com) <grapevinecrc@ventaviaresearch.com>; Dallas CRC Ventavia Group Email (dallascrc@ventaviaresearch.com) <dallascrc@ventaviaresearch.com>; Arlington CRC Ventavia Group Email (arlingtoncrc@ventaviaresearch.com) <arlingtoncrc@ventaviaresearch.com>; Ramirez, Rebecca <Rebecca.Ramirez@iconplc.com>; Stella Alawuru (Stella.Alaw@pfizer.com) <Stella.Alaw@pfizer.com>; Furlow, Danielle <Danielle.Furlow@iconplc.com>; Casteel, Crystal <Crystal.Casteel@iconplc.com>

Subject: RE: Pfizer C3671008 | Crystal's Ventavia Sites | Consider Source Revisions: BMI & ICF Process Documentation

Hello Ventavia Team,

I apologize for sending another email, but wanted to offer another suggestion. I would ask that you consider revising your ICF Process documentation worksheet to capture the ICF "Version" Date and the "ICF Revised Version Date" as this

information is what is provided on the actual ICFs that the SCs have access to vs. IRB approval date, which they need to know off hand, review Advarra CIRB, or check eISF to obtain.

As you can see in the screenshot below, Subject #1058-1006 has the ICF Date error-corrected to the current ICF version date noted per the footer of the ICF (which is correct as 01MAY2020); however, this IRB Approval Date is incorrect as this ICF was IRB-approved on 02JUN2020 and not 01JUN2020, so my co-monitor for Roberts SMV 02 will be issuing a query in EDC to error-correct. I talked to several of my Primary SCs and you all have worked with Advarra before and they do typically have the ICF Revised Version date the same as the IRB App. Date, but I warned to not rely on this solely as it is not always the case, and this is a perfect example.

I am keeping detailed notes of all the approvals at each of your sites and encourage you all to do the same to ensure that most current version is always utilized as applicable for the date the subject consents.

Pfizer C3671008 Source Documents Version 3.1 08Jul2020KW Site 1058 PI: John Paul Roberts, MD
Screening and Vaccination (Visit 1) Day -28 to Day 1

| | | | |
|--|----------------------|--------------------|--------------------|
| Date of Screening and Vaccination Visit: | <u>09 / JUL 2020</u> | | |
| DD | MMM | YYYY | |
| Informed Consent | | | |
| ICF DATE: | <u>09 JUL 2020</u> | IRB Approval Date: | <u>01 JUN 2020</u> |
| DD/MMM/YYYY | DD/MMM/YYYY | | |
| Date / Time Informed Consent Signed: <u>09 / JUL / 2020</u> DD/MMM/ YYYY <u>13:26</u> (24 hr) | | | |
| Signee is: <input checked="" type="checkbox"/> Maternal Study Subject (24-Month) <input type="checkbox"/> Maternal Study Subject (12-Month) Check box if task was completed | | | |

My notes for Dr. Robert's site:

| INFORMED CONSENT DOCUMENT (ICD) VERSIONS - Advarra IRB (No version #'s) - PH#173.23 | | | | | | | |
|---|----|--------------------|----------------------|----------------------------------|----------|------------|--|
| My Versioning | # | Version Date | Revised Version Date | Type (if applicable) | Language | # of pages | Date of IRB Approval / Acknowledgement |
| V1 | 1 | 30-Jan-2020 | 11-Feb-2020 | 12 mo. Main | English | 32 p | 2/1/2020 - 1/31/2021 |
| V1 | 2 | 30-Jan-2020 | 11-Feb-2020 | 24 mo. Main | English | 32 p | 2/1/2020 - 1/31/2021 |
| V2 | 3 | 30-Jan-2020 | 21-Feb-2020 | 12 mo. Main | English | 33 p | 2/21/2020 |
| V2 | 4 | 30-Jan-2020 | 21-Feb-2020 | 24 mo. Main | English | 33 p | 2/21/2020 |
| V3 | 8 | 1-May-2020 | 1-May-2020 | 24 mo. Main | English | 31 p | 5/1/2020 (Letter dated 5/19/2020) |
| V3 | 6 | 8-May-2020 | 8-May-2020 | 12 mo. Main | English | 31 p | 5/1/2020 (Letter dated 5/19/2020) |
| V1 | 5 | 13-May-2020 | 13-May-2020 | 24 mo. Non-maternal Guardianship | English | 26 p | 5/1/2020 (Letter dated 5/19/2020) |
| V1 | 7 | 13-May-2020 | 13-May-2020 | 12 mo. Non-maternal Guardianship | English | 26 p | 5/1/2020 (Letter dated 5/19/2020) |
| V4 | 9 | 1-May-2020 | 1-Jun-2020 | 24 mo. Main | English | 31 p | 6/2/2020 |
| V4 | 10 | 8-May-2020 | 1-Jun-2020 | 12 mo. Main | English | 31 p | 6/2/2020 |
| V2 | 11 | 13-May-2020 | 1-Jun-2020 | 12 mo. Non-maternal Guardianship | English | 26 p | 6/2/2020 |
| V2 | 12 | 13-May-2020 | 1-Jun-2020 | 24 mo. Non-maternal Guardianship | English | 26 p | 6/2/2020 |
| V1 | 13 | 1-May-2020 | 1-Jun-2020 | 24 mo. Main | Spanish | 36 p | 7/9/2020 |
| V1 | 14 | 8-May-2020 | 1-Jun-2020 | 12 mo. Main | Spanish | 35 p | 7/9/2020 |
| V1 | 15 | 13-May-2020 | 1-Jun-2020 | 12 mo. Non-maternal Guardianship | Spanish | 29 p | 7/9/2020 |
| V1 | 16 | 13-May-2020 | 1-Jun-2020 | 24 mo. Non-maternal Guardianship | Spanish | 29 p | 7/9/2020 |
| V5 | 17 | 1-May-2020 | 17-Jul-2020 | 24 mo. Main | English | 31 pages | 7/17/2020 |
| V5 | 18 | 8-May-2020 | 17-Jul-2020 | 12 mo. Main | English | 31 pages | 7/17/2020 |
| V3 | 19 | 13-May-2020 | 17-Jul-2020 | 24 mo. Non-maternal Guardianship | English | 26 pages | 7/17/2020 |
| V3 | 20 | 13-May-2020 | 17-Jul-2020 | 12 mo. Non-maternal Guardianship | English | 26 pages | 7/17/2020 |

Thanks,

Crystal

Crystal Casteel
Senior Clinical Research Associate
Clinical Research Service

Mobile: +1 972-515-0460
Email: Crystal.Casteel@iconplc.com
Web: www.ICONplc.com



PSBU - Partnering Excellence for a Healthier World!

Our team is making a difference by advancing research in the fight against COVID-19
www.iconplc.com/vaccines/

If you need to report a Serious Adverse Event (SAE):
For a Pfizer study, please fax your SAE report to +1.866.997.8322;
For Non-Pfizer studies, please call the SAE Hotline at +1.888.426-8801.
Please DO NOT send SAE information via this email address.

From: Casteel, Crystal <Crystal.Casteel@iconplc.com>

Sent: Wednesday, August 26, 2020 10:51 AM

To: Kandy Downs <kdowns@ventaviaresearch.com>; Marnie Fisher <mfisher@ventaviaresearch.com>; Mercedes Livingston <mercedeslivingston@ventaviaresearch.com>; Rebecca Iacullo <rebeccaiaacullo@ventaviaresearch.com>; Michelle Vernon (michellevernon@ventaviaresearch.com) <michellevernon@ventaviaresearch.com>; Katherine Benitez <katherinebenitez@ventaviaresearch.com>

Cc: Fort Worth CRC Ventavia Group Email (crc@ventaviaresearch.com) <crc@ventaviaresearch.com>; Plano CRC Ventavia Group Email (planocrc@ventaviaresearch.com) <planocrc@ventaviaresearch.com>; Grapevine CRC Ventavia Group Email (grapevinecrc@ventaviaresearch.com) <grapevinecrc@ventaviaresearch.com>; Dallas CRC Ventavia Group Email (dallascrc@ventaviaresearch.com) <dallascrc@ventaviaresearch.com>; Arlington CRC Ventavia Group Email (arlingtoncrc@ventaviaresearch.com) <arlingtoncrc@ventaviaresearch.com>; Casteel, Crystal <Crystal.Casteel@iconplc.com>; Ramirez, Rebecca <Rebecca.Ramirez@iconplc.com>; Stella Alawuru (Stella.Alaw@pfizer.com) <Stella.Alaw@pfizer.com>; Furlow, Danielle <Danielle.Furlow@iconplc.com>

Subject: Pfizer C3671008 | Crystal's Ventavia Sites | Consider Source Revision for BMI

Importance: High

Hello Ventavia Regional Directors, Chief Operating Officers, Site Operations Managers, and Site Managers,

I know that you all have made recent revisions to your source worksheets and I'd like you to consider revising your OB Exam source regarding the BMI. We've previously discussed that you all will update your process by capturing subject's weights at Visit 1 so that the recommended needle size can be confirmed and if the medical records don't capture the subject's height, you all will copy the subject's driver's license and provide this with the source worksheets, or you will confirm & record at Visit 1 (perhaps on the vitals page).

Currently, you all provide an exact calculation of the BMI and with a couple of sites, we've agreed that the moving forward, sites will calculate BMI based on the Adult BMI Calculator from the cdc.gov website: https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html and either record this or print/file this page in the subject's chart.

As the protocol request that you confirm subject's BMI to be < 40 kg/m² via pre-pregnancy or at the 1st OB Appt. during the current pregnancy (must be documented via MRs), would you consider making this a Yes/NO checkbox vs. an exact

value and that way, we can avoid additional queries or any potential findings when the calculations don't match. Screenshot below of source example.

Your thoughts?

Pfizer C3671008 Source Documents Version 3.1 08Jul2020KW Site 1058 PI: John Paul Roberts, MD
Screening and Vaccination (Visit 1) Day -28 to Day 1

| Current Pregnancy (Determination of Gestational Age) | | <input type="checkbox"/> Not Done |
|---|--|-----------------------------------|
| Last Menstrual Period (LMP) known? <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No | *If yes, specify start date of LMP: 15 / JAN / 2020 dd/MMM/YYYY | |
| Comment how/why the subject knows this was her LMP (i.e., app, calendar, etc): Medical records | | |
| What was the subject's BMI prepregnancy? (If prepregnancy BMI is not available, the BMI at the time of the first obstetric visit during the current pregnancy may be used) | 25.3 kg/m ² (If BMI is >40 kg/m ² , subject will be screenfailed) | |
| Was first-trimester ultrasound performed? <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No | *If yes, date performed: ____ / ____ / ____ dd/MMM/YYYY | |

Kind regards,
Crystal

Crystal Casteel
Senior Clinical Research Associate
Clinical Research Service

Mobile: +1 972-515-0460
Email: Crystal.Casteel@iconplc.com
Web: www.ICONplc.com



PSBU - Partnering Excellence for a Healthier World!

Our team is making a difference by advancing research in the fight against COVID-19
www.iconplc.com/vaccines/

If you need to report a Serious Adverse Event (SAE):
For a Pfizer study, please fax your SAE report to +1.866.997.8322;
For Non-Pfizer studies, please call the SAE Hotline at +1.888.426-8801.
Please DO NOT send SAE information via this email address.

ICON plc made the following annotations.

This e-mail transmission may contain confidential or legally privileged information that is intended only for the individual or entity named in the e-mail address. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or reliance upon the contents of this e-mail is strictly prohibited. If you have received this e-mail transmission in error, please reply to the sender, so that ICON plc can arrange for proper delivery, and then please delete the message.

Thank You,

ICON plc
South County Business Park
Leopardstown
Dublin 18
Ireland
Registered number: 145835

Ex. 20

Rebecca Gibson

From: Jennifer Valo <jvalo@ventaviaresearch.com>
Sent: Thursday, September 24, 2020 4:08 PM
To: Jen Vasilio
Cc: Marnie Fisher; William Jones; Dana Duvak; Brook Jackson
Subject: Re: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Jen,

I just wanted to make sure you are aware of this email and all patients that were not put in Impala directly after the ICF need to have a protocol deviation written up (only on the log, not reported).

These have NOT been flagged for you, since we were waiting on the response, so if you can also let the other girls know.

Thank you ma'am.

Jennifer Valo
NRCMA, Project Manager

Ventavia Research Group
710 Eureka St.
Weatherford, Tx 76086
Office: 817-925-5808
Cell: 817-975-8791
Fax Number: 888-660-1080
Email: jvalo@ventaviaresearch.com



Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

From: Jennifer Valo <jvalo@ventaviaresearch.com>
Sent: Thursday, September 24, 2020 4:04 PM
To: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>; Dana Duvak <danaduvak@ventaviaresearch.com>

Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; William Jones <wjones@ventaviaresearch.com>; Jen Vasilio <jvasilio@ventaviaresearch.com>

Subject: Re: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Thank you sir.

Jennifer Valo

NRCMA, Project Manager

Ventavia Research Group

710 Eureka St.
Weatherford, Tx 76086
Office: 817-925-5808
Cell: 817-975-8791
Fax Number: 888-660-1080
Email: jvalo@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

From: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>

Sent: Thursday, September 24, 2020 3:27 PM

To: Jennifer Valo <jvalo@ventaviaresearch.com>; Dana Duvak <danaduvak@ventaviaresearch.com>

Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; William Jones <wjones@ventaviaresearch.com>; Jen Vasilio <jvasilio@ventaviaresearch.com>

Subject: RE: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Yes, it is a deviation.

Arturo A. Alfaro, M.D.

Site Relationship Partner II

Global Site & Study Operations

Clinical Development & Operations, GPD

Location: North America, United States, C.S.T.

Office / Cell: 512-638-2188

Fax: 845-474-5793

arturo.alfaro@pfizer.com



Breakthroughs that
change patients' lives

From: Jennifer Valo <jvalo@ventaviaresearch.com>

Sent: Thursday, September 24, 2020 3:01 PM

To: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>; Dana Duvak <danaduvak@ventaviaresearch.com>

Cc: Marnie Fisher <mfisher@ventaviaresearch.com>; William Jones <wjones@ventaviaresearch.com>; Jen Vasilio <jvasilio@ventaviaresearch.com>

Subject: [EXTERNAL] Re: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Ok we agree with that! The only thing that was done out of any type of order was the subject being put in Impala to get the screening number. It was not done directly after the consent process. It was done before randomization obviously but that is the only thing that was done out of order.

So just to verify, this would or would not be a deviation?

Jennifer Valo

NRCMA, Project Manager

Ventavia Research Group

710 Eureka St.
Weatherford, Tx 76086
Office: 817-925-5808
Cell: 817-975-8791
Fax Number: 888-660-1080
Email: jvalo@ventaviaresearch.com



PLATINUM
RESEARCH NETWORK

<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

From: Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>

Sent: Thursday, September 24, 2020 1:35 PM

To: Jennifer Valo <jvalo@ventaviaresearch.com>; Dana Duvak <danaduvak@ventaviaresearch.com>

Subject: RE: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Hello;

I actually got some clarification from the clinicians. It is not necessarily a protocol deviation. However, there are some procedures that need to be completed before randomization, like blood draw, physical exam. There is going to be a study communication clarifying this item shortly.

Let me know if you have any questions.

Arturo A. Alfaro, M.D.

Site Relationship Partner II

Global Site & Study Operations

Clinical Development & Operations, GPD

Location: North America, United States, C.S.T.

Office / Cell: 512-638-2188

Fax: 845-474-5793

arturo.alfaro@pfizer.com



From: Alfaro, Arturo A.

Sent: Tuesday, September 22, 2020 9:32 AM

To: Jennifer Valo <jvalo@ventaviaresearch.com>; Dana Duvak <danaduvak@ventaviaresearch.com>

Subject: RE: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Hi Jennifer;

Sorry for my late response. Yes, it should be considered a deviation.

Arturo A. Alfaro, M.D.

Site Relationship Partner II

Global Site & Study Operations

Clinical Development & Operations, GPD

Location: North America, United States, C.S.T.

Office / Cell: 512-638-2188

Fax: 845-474-5793

arturo.alfaro@pfizer.com



From: Jennifer Valo <jvalo@ventaviaresearch.com>

Sent: Tuesday, September 22, 2020 8:23 AM

To: Dana Duvak <danaduvak@ventaviaresearch.com>; Alfaro, Arturo A. <Arturo.Alfaro@pfizer.com>

Subject: [EXTERNAL] Re: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Good morning Arturo,

I wanted to follow up with you on this email that Dana sent you yesterday to see if you had an answer on how we should proceed with this?

Jennifer Valo

NRCMA, Project Manager

Ventavia Research Group

710 Eureka St.

Weatherford, Tx 76086

Office: 817-925-5808

Cell: 817-975-8791

Fax Number: 888-660-1080

Email: jvalo@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.

From: Dana Duvak <danaduvak@ventaviaresearch.com>

Sent: Monday, September 21, 2020 11:10 AM

To: Arturo.Alfaro@pfizer.com <Arturo.Alfaro@pfizer.com>

Cc: Jennifer Valo <jvalo@ventaviaresearch.com>

Subject: Pfizer - C4591001 - COVID-19 Vaccine - Protocol Question

Good afternoon, Dr. Alfaro

I am hoping you can provide me with some clarification regarding the protocol visit procedures.

The protocol states that the visit procedures are anticipated to be completed in a stepwise manner. However, if a procedure was not performed in a stepwise manner, should it be recorded as a protocol deviation? For example, the IWRS screening ID was not assigned until after the vital signs.

Thank you for your help!

Dana Duvak, CCRC

Project Manager

Ventavia Research Group

1307 8th Ave Suite #202

Fort Worth, TX 76104

Office Number: 817-348-0228

Cell Number: 817-694-6998

Fax Number: 817-394-1901

Email: danaduvak@ventaviaresearch.com



<https://www.ventaviaresearch.com/>

<http://www.platinum-research.net/>

Privacy Notice: Ventavia Research Group, LLC. This transmission is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any disclosure, dissemination, distribution or copying of the communication is strictly prohibited. If you have received this communication or any associated attachments in error, please notify the sender immediately. Thank you in advance.